and eggs laid by the birds of antibody in the yolk and albumin of the eggs to CA antigen from C.aminophilium;

C. Harvesting the eggs laid by the birds;

D. Separating the antibody[-containing contents] yolk and albumin of said harvested eggs from the egg shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the antibody[-containing contents] yolk and albumin of the harvested eggs;

G. Distributing said carrier material coated with the antibody[-containing contents] yolk and albumin of the eggs substantially uniformly in animal feed; and

H. Supplying the resulting antibody[-containing contents] yolk and albumin and animal feed to food animals to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

REMARKS

Reconsideration of this application and entry of this amendment is requested to place the application in condition for allowance or better form for an appeal.

The application contains Claims 10, 11 and 15 to 23 which define methods of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The method inhibits the ability of the target protein wasting immunogen from adhering to the rumen or intestinal tract of the animals. This reduces the ability of the protein wasting immunogen to multiply in the rumen and digestive tract of the animal. The available protein is not reduced by the immunogen whereby more protein is utilized by the animals to promote growth. The increase

in dietary protein in vivo results in feed efficiency and increases in growth of the animals. The control of growth of this organism in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The protein-wasting immunogen is from a class consisting of P.anaerobius, C.sticklandii and C.aminophilium. These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Pages 23 and 24.*

The claims are presented in two groups. Group I comprises Claims 10, 11 and 14 to 16. Group II comprises Claims 17 to 32.

Group I claims include the process of separating the antibody yolk and albumin material or entire contents of the eggs from the shells. The yolk and albumin material is dried to provide a dried egg antibody product. This product is mixed with animal feed or water which is supplied to animals. The result is that the immunogen is substantially prevented from adhering to the intestinal tract of the animal. This predicates the function of the claimed method.

Group II claims include the process of providing a dry feed carrier material. The carrier material is coated with the antibody yolk and albumin material. The dry feed carrier material absorbs moisture from the antibody yolk and albumin material thereby drying the antibody yolk and albumin on the carrier material. The use of the carrier material helps distribute the antibody yolk and albumin in a uniform method in the animal feed. The carrier material coated with the antibody yolk and albumin makes it easier for mixing with standard feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with the antibody yolk and albumin is supplied to the animals. The antibody yolk and albumin binds with the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the immunogen in the intestinal tract of the animal.

Claims 10, 17, 19, 21, 23, 25, 27, 29 and 31 have been amended to more specifically

define applicants' method of promoting the growth of food animals. The method includes the separation of the whole egg contents (yolk and albumin) from the shells of the eggs. The whole egg contents includes IgY type immunoglobulins as disclosed on page 10, lines 21 to 23 and page 11, line 1 of the specification. The whole egg is disclosed in Examples 11, 19, 21, 23, 24 and 27.

Applicants have discovered that the albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the intestinal tract. Albumin is a protein that protects the activity of the IgY type immunogobulins thereby increasing its active life in the intestinal tract. The result is that use of the antibody yolk and albumin mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the intestinal tract of the animal.

It is clear that applicants' claimed method of promoting the growth of food animals is not obvious from the teachings of *Krause et al* and *Tokoro et al*. There are no motivating directions in these references that would impel one skilled in the art to do the claimed method.

The test for determining obviousness of a claimed invention under 35 USC 103 is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force

which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden *only* by showing some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of P.anaerobius and C.sticklandii in the rumen of an animal but did not inhibit C.aminophilum. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an

animal.

Tokoro et al discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolk of the eggs. The yolk is separated from the albumin. The yolk is homogenized and dried to form a powder. The powder administered to the animal by the oral route is useful for the prevention and treatment of colibacillosis and diarrhea in animals. *Tokora et al* does not teach the use of albumin IgM and IgA in conjunction with yolk IgY to inhibit adherence of targeted immunogens in the intestinal tract of an animal thereby inhibiting colony growth of the targeted immunogen and promoting growth of the food animal.

Claims 17 to 32 have been rejected under 35 USC 103(a) as unpatentable over *Krause et al* and *Tokoro et al* as applied to Claims 10 to 11 and 14 to 16 and further in view of *Betz et al* and *Adalsteinsson et al.* The amendments and remarks concerning Claims 10 to 11 and 14 to 16 are applicable to Claims 17 to 32. *Betz et al* and *Adalsteinsson et al* do not add to the teachings of *Krause et al* and *Tokoro et al.*

Adalsteinsson et al does not teach coating a dry feed carrier with an antibody yolk and albumin of eggs to dry the antibody yolk and albumin. Dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder.

Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls or cottonseed hulls. The *Betz et al* animal feed is a mixture of materials including three hulls coated with a vegetable oil. The hulls are not used to dry any feed materials.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier material by *Betz et al* and *Adalsteinsson et al*, it would not have been obvious to a persons skilled in the art to make and use the method defined in Claims 17 to 32.

This application was filed on July 14, 2000. The first Office action dated November 9,

2000, was a restriction requirement between Claims 1 to 3, 4 to 9, 10 to 11 and 12 to 13. Prior art was not considered by the examiner in this Office action. Applicants elected the invention defined in Claims 10 and 11. The second Office action dated February 9, 2001, was limited to Claims 10 and 11. Applicants filed amendments dated September 18, 2001 and October 18, 2001, to the specification and added Claims 14 to 16 and 17 to 32. An amended specification was filed on December 18, 2001. Applicants received an Office action on January 2, 2002, on the merits of Claims 10 to 11 and 14 to 32. This Office action included new prior art, *Betz et al 4,166,867* and *Adalsteinsson et al 6,086,878*, applied to Claims 17 to 32. The present amendment is responsive to the Office action of January 2, 2002. The amendment is timely as it more particularly defines the claims and is responsive to the new and first grounds of rejection of Claims 17 to 32. Applicants request that the amendment be entered in this application and that Claims 10 to 11 and 14 to 32 be allowed.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on _____,

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Richard O. Bartz
Signature

May 16, 2002
Date of Signature